

REMARKS

The present amendment is in response to the Official Action dated October 18, 2005. Claims 1-25 and 27-30 have been cancelled. Claim 26 has been amended. Claims 31-38 are new. Therefore, claims 26 and 31-38 remain in the application and are currently pending. The following sets forth the Applicant's arguments relating to the presently pending claims.

In the Official Action, the Examiner first objected to claims 25, 27 and 28 due to certain informalities relating to their respective dependency. Given that each such claim has been cancelled in the present amendment, there is no need to address these objections. Further, in the Official Action, the Examiner has rejected claims 1, 2, 19, 20 and 30 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,895,426 to *Scarborough* ("*Scarborough*"). Essentially, the Examiner asserts that *Scarborough* teaches an intervertebral prosthesis that is comprised of cancellous bone and thusly teaches all the elements of claim 1. In addition, the Examiner opines that *Scarborough* also teaches a procedure of spinal fusion utilizing cancellous bone, and as such, concludes that *Scarborough* anticipates independent claims 19 and 30, which claim methods for performing spinal fusion surgery by implanting a graft of substantially cancellous bone between lumbar or thoracic vertebral bodies.

Still further in the Official Action, the Examiner has also rejected claims 1, 2, 8, 11-13, 15, 19-21 and 26-29 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2003/0028197 (now U.S. Patent No. 7,018,416) to *Hanson, et al.* ("*Hanson*"). The Examiner contends that *Hanson* teaches an implant made of bone, which may be an allograft graft derived from the calcaneus. In addition, the Examiner also asserts that *Hanson* discloses a preferred embodiment of the bone implant that may be constructed of cancellous (possibly

surrounded by cortical bone) and provides examples of obtaining single pieces of allograft. Moreover, the Examiner asserts that the *Hanson* reference shows that the implant must be capable of bearing the weight of a human being, and therefore, the Examiner concludes that claims 1, 2, 8, 11-13 and 15 are anticipated by that reference. Similar to the above discussion relating to the method claims in light of *Scarborough*, the Examiner also asserts that *Hanson* inherently teaches the method steps of claims 19-21 and 26-29.

Finally, the Examiner has also rejected claims 3-7, 9, 10, 14, 16-18, 22-25 and 30 under 35 U.S.C. § 103(a) as being obvious over both *Scarborough* and *Hanson*. In short, it is the Examiner's opinion that although *Scarborough* does not specifically teach the limitations of claims 3-7, 9, 10 and 22-25, such would have been obvious to one of ordinary skill in the art at the time the invention was made. It is also the Examiner's opinion that although not specifically taught by *Hanson*, the additional limitations of claims 3-7, 9, 10, 14, 16-18, 22-25 and 30 would also have been obvious to one of ordinary skill in the art at the time the invention was made. Nevertheless, given the aforementioned cancellations of claims 1-25 and 27-30, as well as the amendments to claim 26 and the addition of new claims 31-38 in the present application, it is respectfully submitted that neither the *Scarborough* nor *Hanson* references anticipate or render obvious the currently pending claims.

More particularly, independent claim 26 has been amended to include the limitations originally presented in dependent claims 27 and 29. Specifically, the sole independent claim now requires that a method of making an allograft lumbar or thoracic spine implant include the steps of "cutting a portion of the cancellous bone from a donor in a size and shape for insertion between two vertebral bodies, wherein a plurality

of cross-sections are cut substantially perpendicular to the long axis and from a central portion of the calcaneus," and "cutting the portion to provide two or more sub-sections to provide an implant for use in the transforaminal lumbar interbody fusion or posterior interbody lumbar fusion." In other words, sole independent claim 26 remains directed to a method of making an allograft spine implant, but now not only includes a single step of cutting a portion of the calcaneus in a size and shape for insertion between two vertebral bodies, but also that a plurality of cross-sections be cut from the calcaneus and that the portion be cut into two or more additional subsections. This is a novel method which allows the created implant to be used in a transforeminal lumbar interbody fusion or posterior interbody lumbar fusion procedure, something which is not taught nor suggested by either *Scarborough* or *Hanson*. Rather, the *Scarborough* reference teaches a unitary bone graft implant which may be cut using a specialized tool, and *Hanson* teaches cutting a bone implant, but is silent as to the specific method for cutting such implant. Thus, the Examiner's initial rejection of dependent claim 29, in Applicant's opinion, was unfounded. As neither *Scarborough* nor *Hanson* teach or suggest all of the limitations of newly amended sole-independent claim 26, Applicants respectfully submit that such claim is neither anticipated nor obviated by those references.

Therefore, in light of all the above, it is respectfully requested that independent claim 26 be moved into a condition of allowance. In addition, it is also noted that new claims 31-38 have been added to further limit amended claim 26. Although such claims include limitations set forth in previously rejected claims, such should be allowed for the mere reason that newly amended independent claim 26 is neither anticipated nor

suggested by any of the prior art of record. Thus, Applicant respectfully requests allowance of claims 26 and 31-38.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone Applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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